syringe body (1) and a removable cap (4) engageable on said plastic hollow spike (9) to close said syringe body (1);

wherein said plastic hollow spike (9) includes means for piercing the elastomeric closure (11) of the medical container (10), said plastic hollow spike (9) is conical and tapered and said plastic hollow spike (9) is provided with a bevel (9a) extending over an entire diameter of said plastic hollow spike at a piercing end of said spike (9).

REMARKS

Applicants have indeed elected to prosecute claims for the species of Fig. 6 without traversal.

Claims 1, 3, 5 and 6 were rejected as anticipated under 35 U.S.C. 102 (b) by Goodsir, et al.

New independent claim 18 includes **all** the features and limitations of canceled independent claim 1 and dependent claims 3, 5 and 6. Also a new dependent claim 19 has been filed to claim the embodiment with the cap 4 as shown in Fig. 6. A new more limited independent claim 20 limited using "consisting of" has also been filed including the cap 4.

Furthermore the term "plastic hollow spike" in the claims has been changed to "plastic hollow spike". Basis for this change appears on page 5, line 8, and following of applicants' originally filed specification. The plastic hollow peg

is limited to a hollow spike having a bevel that is like a thorn, thus making it easy for it to penetrate an elastomeric closure as described on page 5 of the specification.

Goodsir, et al, disclose a needless syringe (Fig. 1) with a plastic barrel 10 and with a fluid transfer tube 14 made of rigid plastic and "extending into and secured to" the barrel (claim 1 of Goodsir, et al, lines 27 to 29). A tapered and approximately conical hub connector 16 is used to secure the transfer tube 14 in the plastic barrel 10. The front end of the hub connector 16 has a nose 21 with an annular ring 22 (also called tubular forward extension, column 1, line 54 to 56), which engages in a female fitting of a valve actuated intravenous port. The nose 21 and the ring 22 are formed and arranged so that they can "bear upon and open" (column 3, line 45 to 46) a member 60 of the valve in the intravenous port (Fig. 2) by displacement of valve disk 50. The valve closes again when the syringe is withdrawn from the intravenous port.

Goodsir, et al, do not disclose several limitations that are included in the new claim 18.

First, Goodsir, et al, do not disclose that their syringe has a plastic hollow spike 9 that is conical and tapered, provided with a bevel at a piercing end and in one piece with the syringe body 1. The hub connector 16 is approximately conical and tapered but is not **in one piece** with the syringe body: it is a separate part (see the figures of the reference). Nothing in the Goodsir reference would limit the syringe to a syringe having a hub connector in one piece with the syringe body. Also claim 18 is limited to a hollow spike 9, which is in one piece with the

syringe body. The transfer tube 14 is neither tapered nor conical, so that it cannot be interpreted as the hollow plastic spike 9. Also the reference does not state that the transfer tube 14 should be in one piece with the syringe body. The front end portion of the syringe body itself of the Goodsir reference is clearly not equivalent to the hollow plastic spike 9, because it does not include means for piercing an elastomeric closure or means for opening the valve: in the syringe of Goodsir the means for opening the valve is at the front end of the hub connector 16. Furthermore the front end of the syringe body itself is not beveled, and does not need to be beveled or tapered for any purpose because of the presence of the transfer tube 14 and the hub 16.

Furthermore Goodsir, et al, do not disclose means for **piercing** an elastomeric closure. To "pierce" something means to penetrate it or make a hole in it. The tubular forward extension of Goodsir, et al, does not "pierce" the valve disk 50 (column 3, lines 45 to 50; column 4, lines 10 to 15). Instead it pushes it as the forward extension is inserted in the female connector and thus opens the valve. Thus Goodsir, et al, disclose no means for piercing an elastomeric closure.

It is well established that each and every limitation of a claimed invention must be disclosed in a single prior art reference that is used to reject the claimed invention as anticipated under 35 U.S.C. 102 (b) for a valid anticipation rejection. See M.P.E.P. 2131 and the references cited therein including *In re Bond*.

In the case of the instant claim 18 Goodsir, et al, do not disclose that the front end of the syringe or the plastic hollow spike (9) have **means for piercing** an elastomeric closure.

Also since **neither** the front end of the forward extension 21 with the annular ring 22 **nor** fluid transfer tube 14 need to pierce or penetrate an elastomeric closure or anything, as in the case of applicants' syringe device of claim 18, there is **no** need for either a tapered end or a bevel on the front end of either. The syringe of Goodsir, et al, thus does **not** have either a tapered front end, or a front end with a bevel. It does not have a hollow spike at the front end with a tapered end or a bevel that is in one piece with the syringe body.

For the foregoing reasons it is respectfully submitted that new claims 18 and 19 should **not** be rejected under 35 U.S.C. 102 (b) as anticipated by Goodsir, et al.

The front end of the syringe device of Goodsir, et al, does not need to be tapered and it is not. Neither the hub 16 nor the transfer tube 14 need to include means for **piercing** an elastomeric closure, because the front end is not used for that purpose.

Thus there is nothing in the art that would suggest including a means for **piercing** (as opposed to pushing or displacing) at the front end of the syringe of Goodsir, et al (particularly since it is not needed for the intended use).

It is well established by many U. S. Court decisions that to reject a claimed invention under 35 U.S.C. 103 there must be some hint or suggestion in the prior art of the modifications of the disclosure in a prior art reference or references used to reject the claimed invention, which are necessary to arrive at the claimed invention. For example, the Court of Appeals for the Federal Circuit has said:

"Rather, to establish obviousness based on a combination of elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant...Even when obviousness is based on a single reference there must be a showing of a suggestion of motivation to modify the teachings of that reference.." *In re Kotzab*, 55 U.S.P.Q. 2nd 1313 (Fed. Cir. 2000). See also M.P.E.P. 2141

For the foregoing reasons it is respectfully submitted that new claims 18 and 19 should **not** be rejected under 35 U.S.C. 103 (a) as obvious from Goodsir, et al. The same is true of new claim 20.

Claims 1, 3, 5 and 6 were rejected under 35 U.S.C. 102 (b) as anticipated by Heinke.

Heinke discloses a method of delivering a pharmaceutical composition to a living creature, especially into the nose of the creature, and a specially structured syringe designed for that method.

The methods of Heinke and applicants do clearly differ because the method of Heinke involves delivery of the syringe contents into the nose of an animal or human while in the case of applicants the syringe of claim 18 is designed to deliver the contents of the syringe into an infusion container.

Furthermore the syringe claimed in claim 18 and canceled claim 6 does differ in one way from the syringe disclosed in the Heinke U.S. Patents.

Heinke, et al, do not disclose a "means for piercing" an elastomeric

closure that is equivalent to applicants' means. In accordance with M.P.E.P. 2184 under "Factors to be considered in Deciding Equivalence" (under the sixth paragraph of 35 U.S.C. 112) the "means for piercing" the elastomeric closure of Heinke must perform the same function in the same manner to achieve the same result to be equivalent. The standard type of needle that comes to a point as in Fig. 2 of Heinke '599 is conical like the excluded species of Figs. 10 to 12 and comes to a sharp point, which can injure a user. However it does not function in the same manner as applicants' "means for piercing". Applicants' "means for piercing" comprises the plastic hollow spike **with the beveled end**. The **bevel** is absent from the needle of Heinke, but the hollow spike is safe than a needle that comes to a point, while being easier to penetrate a tough elastomeric closure than a blunt peg.

The differences between the tip of the needle of Heinke and applicants' plastic hollow spike are not insubstantial. The plastic hollow spike is safer and not as likely to cause injury to a user, but because of the bevel easily penetrates an elastomeric closure of a medical container.

Heinke, et al, do not disclose the plastic hollow spike with the bevel that provides a thorn-like or knife-like cutting edge for penetrating the elastomeric closure easily.

It is well established that a prior art reference must disclose each and every feature of a claimed invention in order to reject the claimed invention as anticipated under 35 U.S.C. 102 (b) based on the prior art reference.

For the foregoing reasons and because of the features and limitations

claimed in the new claims 18 and 19 it is respectfully submitted that Heinke cannot be used to reject claims 18 and 19 as anticipated under 35 U.S.C. 102 (b).

In addition new claim 20, which is limited using "consisting of " wording, claims a preferred embodiment.

Thus new claim 20 should not be rejected as anticipated under 35 U.S.C. 102 (b), or as obvious under 35 U.S.C. 103 (a), based on Heinke or Goodsir, et al.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Any costs involved should be charged to the deposit account of the undersigned (No. 19-4675). Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

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